Data Visualisation & Open Source Technology

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Clinical Visual Analytics for Review and Submission (CVARS)

Description

The Clinical Visual Analytics for Review and Submission Project aims to support the community by addressing key questions and challenges related to data visualisation and open-source tools.

These areas naturally align in the current landscape, where open-source programming languages offer powerful and flexible data visualisation capabilities. By exploring this intersection, the Working Group seeks to promote effective use of modern tools, share best practices, and improve understanding of how open-source technologies can enhance data visualisation in a regulatory and clinical context.

Q2 2026

Proposed End Date

An open-source R Shiny tool

Deliverable

- Presented at MBSW, generating strong discussion among statisticians on the FDA pilot, modular programming, and the challenges of bundling solutions for FDA submission (validation + AI integration).
- Surfaced a new direction from the FDA's R Consortium/FDA pilots presentation: enabling WebR support, now flagged as an area to explore.

Key Achievements This Quarter:

AI integration remains on the future roadmap, with trust and validation concerns still to be addressed. We're also reaching out to the ASA BIOP AI Nexus initiative, where the same trust/validation issues are being discussed and where there is FDA presence from various groups working on this topic.

Deliverables & Targets Planned for the Next Quarter:

Melvin Munsaka, Neetu Sangari & Jiang Hu

Leads

Project Status: Green
Accepting New Members

- Two activities are ongoing and not yet complete. The project won't wrap at the end of the quarter as previously assumed, due to the programmer's departure; progress is delayed until their replacement settles in.

Project Status

Communication of Version Metadata for Open-Source Languages

Description

This project aims to develop or enhance a standard template (such as the Study Data Standardisation Plan [SDSP] or Analysis Data Reviewer's Guide [ADRG]) to ensure consistent documentation of metadata related to statistical package versions and procedures. The goal is to align with health authority expectations and streamline the submission of clinical study metadata as part of the regulatory review process.

Historically, with proprietary statistical programming languages, version information has typically been captured at a high level within the SAP, often as a general statement of the software and version used. However, with the increasing adoption of open-source technologies, more detailed and transparent metadata is now required. This project will address this gap by enabling structured, standardised capture of package-level metadata, supporting improved traceability, clarity and regulatory confidence.

Q3 2026

Proposed End Date

White paper

Deliverable

Key Achievements This Quarter:

- Contributed as a separate workstream to the PHUSE ADRG Working Group, which is responsible for the overall ADRG package (templates and examples across tools such as SAS and R)
- Provided input to the ADRG template for open-source (R) use
- Delivered completion guideline for R submissions (now handed over to the ADRG Working Group and under final review)
- Progressed development of supporting R-based approaches for version metadata

Deliverables & Targets Planned for the Next Quarter:

- Complete the ADRG example for an R (open-source) submission and hand over to the ADRG Working Group.
- Support integration of open-source components into the broader ADRG package.

Joel Laxamana & Lovemore Gakava

Leads

Project Status: Green
Accepting New Members

- The ADRG Working Group is progressing the full ADRG package (templates and examples across tools).
- Our group has focused on the open-source (R) components and is transitioning these deliverables to the ADRG Working Group.
- Remaining work is centred on finalising the R example and closing outstanding template actions.

Project Status

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Comparing Analysis Method Implementations in Software (CAMIS)

Description

The CAMIS (Comparing Analysis Method Implementations in Software) project builds on the earlier Clinical Statistical Reporting in a Multilingual World initiative, addressing differences observed in statistical results across programming languages. Even within validated environments, variations in underlying computational approaches can produce results that differ but remain statistically valid. These discrepancies create uncertainty for sponsor companies when submitting to regulatory agencies, particularly regarding how such differences will be interpreted.

CAMIS aims to define this challenge and provide a structured framework for assessing cross-language differences in statistical analyses. The project focuses on key analyses commonly used in submissions (e.g. summaries, models, bioequivalence testing), documents where equivalence can be achieved and evaluate known differences through practical use cases. It also provides sample code via a public repository and promotes statistically sound implementation choices over software-specific defaults, supporting greater confidence in multi-language regulatory submissions.

The CAMIS repository to document known differences is now live and open for community contributions.

Ongoing

Proposed End Date

White paper & open-source collaboration repository

Deliverable

- Accelerated failure time (AFT) models completed (a minor revision is still outstanding, but the content is essentially done).
- Weighted log-rank survival method completed and submitted within the last month.
- Reduced the open issue count to 21, down from an original total of 146 closed, reflecting steady progress against the higher-priority statistical methods over the past three years.
- Continued community-driven contributions, with external experts identifying niche stats areas and authoring content, which leadership then moderates.

Key Achievements This Quarter:

- Conference poster presentation (taking place next week).
- Strategic review of all open and assigned issues to confirm whether current assignees are still actively working items or whether they should be reassigned, allowing the group to take a more proactive rather than reactive approach to its roadmap.
- Continued progress on outstanding methods, including MMRM, which leadership intends to pick up directly to move it forward.
- Increase the cadence and reach of CAMIS blog posts to better publicise the project's work.

Deliverables & Targets Planned for the Next Quarter:

Lyn Taylor, Christina Fillmore & Yannick Vandendijck

Leads

Project Status: Green

- Work is progressing well. AFT models and the weighted log-rank method are complete; the conference poster is in progress. The leadership team meets every two weeks, with a wider project team meeting monthly (typically six or seven attendees). Because much of the work depends on external contributors, individual timelines are not fully within the team's control, and the upcoming issue review is intended to address stalled items.

Project Status

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Demonstrating Real-World Impact of Modernization of Statistical Analytics (MSA) Framework

Description

The PHUSE project team will extend the MSA framework by developing a reference architecture grounded in real-world use cases. This work will identify common implementation challenges and propose practical design solutions to address associated risks, providing clear guidance for building a validated, end-to-end environment for regulated activities. While the MSA framework offers flexible, open-source guidance for regulatory reporting, its adaptability can create implementation complexity and gaps in risk mitigation.

Building on the original 2021 TransCelerate framework, which established the conceptual foundation but did not include demonstrable solutions, the PHUSE handover will focus on practical application. This includes showcasing how the framework can be implemented using real tools and workflows, helping organisations move from theory to operational adoption with greater confidence and consistency.

Q3 2026

Proposed End Date

White paper

Deliverable

Benjamin Chiang, Lu Yao & Neil Ward

Leads

Completed an in-depth, end-to-end analysis of all data flows of the framework (Rave to Submission, board item #21), working through the data flows used within member companies, identifying the technical components in those workflows, how they connect, and how they map to the tenets of the original MSA white paper.

Key Achievements This Quarter:

Architecture diagram visual improvements: refining how the framework information is presented

Architecture diagram: architectural approach revision

Architecture testing: stand up physical testing where appropriate/possible. (This item is contingent on infrastructure availability; no one currently has the infrastructure to perform the testing, so it may proceed only on a speculative basis or based on what members can do within their respective companies.)

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green

- Work is progressing well and the planned items are on track for Q3. The team is currently focused on visual improvements to how the framework information is presented. The architecture testing item carries a caveat: it may or may not be completed this quarter, depending on infrastructure resources.

Project Status

Open Source Technology Adoption in Japan

Description

This project aims to promote the practical adoption of open-source technology (OST) in clinical development in Japan by strengthening knowledge-sharing and providing community-driven resources. It focuses on supporting practitioners through case studies, practical guidance, training materials, and small-scale tools such as R-based utilities, rather than addressing regulatory policy.

Despite increasing global adoption, OST use in Japan remains cautious and inconsistent, limiting the industry's ability to fully realise its benefits. This project seeks to address these challenges by improving access to shared knowledge and real-world examples, particularly in clinical development and real-world data (RWD) analytics.

By enhancing collaboration and providing practical resources, the initiative will support more informed adoption decisions, reduce duplicated effort, encourage consistent practices, and improve overall efficiency and reproducibility within the Japanese clinical research community.

Proposed End Date

Q4 2026

Deliverable

Presentation at a PHUSE Single Day Event

Key Achievements This Quarter:

Started preparation for the next PHUSE SDE presentation.

Deliverables & Targets Planned for the Next Quarter:

Continue preparation of presentation materials.

Leads

Tomoki Nishikawa & Yuichi Nakajima

Project Status

Project Status: Green

- The project has moved from the initial planning phase into the preparation phase.

PharmaForest: collaborative repository of SAS packages for pharmaceutical industry

Description

This project aims to drive adoption of reusable SAS packages and best practices across the pharmaceutical industry, addressing inefficiencies, fragmentation and limited collaboration. It focuses on establishing an open, sustainable ecosystem - PharmaForest - built on the SAS Packages Framework (SPF) to improve productivity, compliance and knowledge sharing.

Key activities include developing educational materials and presentations on implementing PharmaForest packages and SPF, and sharing these through webinars, industry events (e.g. PHUSE Connect) and training sessions. The project will also create and maintain an open-source repository of high-quality SAS packages for common pharmaceutical use cases, enabling consistent installation and version control.

By fostering community engagement through contributions, peer review and onboarding resources, PharmaForest will reduce duplicated coding, improve standardisation and enhance quality. This approach will accelerate development timelines, lower costs, strengthen compliance and support a more collaborative and innovative SAS programming community.

Ongoing

Proposed End Date

Workshop & guidance materials

Deliverable

Hiroki Yamanobe, Ryo Nakaya & Yutaka Morioka

Leads

Held a meeting with project members and volunteers.

Key Achievements This Quarter:

Present at the Kagoshima Data Science Symposium.

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- The team held its project members/volunteers meeting in May. Preparation for a presentation at the Kagoshima Data Science Symposium is in progress, targeted for the end of June. Q2 statuses have been updated on the project board.

Project Status

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Teal Enhancements for Cross-Industry Adoption

Description

This project aims to enhance the teal framework by increasing its flexibility for use across pharmaceutical companies. Through research, development, testing, documentation and training, it will introduce new functionality that allows users to reformat, post-process and decorate outputs from existing teal modules without changing the core code.

While teal and teal.modules.clinical already provide strong support for interactive exploration of standardised clinical data, differences in company standards and analysis requirements have limited broader adoption. As a result, organisations often build custom modules from scratch, creating unnecessary effort and inefficiency.

By enabling customisation of tables, graphs and listings through reusable enhancements, this project will reduce the need for bespoke development, improve scalability of existing modules, and support greater consistency across the industry. Overall, it will make teal more practical, adaptable and widely usable in pharmaceutical workflows.

Q2 2027

Proposed End Date

Presentations, training & deployment of proposed enhancements of the teal framework

Deliverable

- Published teal.picks to CRAN.
- Added the new Report Manager feature to uteals, now open source and available for use.
- Successfully completed the teal and uteals Hackathon and presented it at the R in Medicine conference.
- Began work on a feature allowing CSV file downloads from reports in uteals (in progress).

Key Achievements This Quarter:

- Collaborate with the gtsummary maintainer (Daniel) to address performance issues when generating teal modules that use gtsummary as the engine. The UTL/Working Group team is already meeting with Daniel; the work is in progress, with a readout expected next month.
- Initiate development of a comprehensive tutorial and adoption guide, with publication planned for Q4 2026.
- Complete the in-progress CSV download feature for reports in uteals.

Deliverables & Targets Planned for the Next Quarter:

Peyman Eshghi, Nicholas Masel & Nina Qi

Leads

Project Status: Green
Accepting New Members

- The project had a productive quarter, with teal.picks published to CRAN, the Report Manager added to uteals, and a successful Hackathon presented at R in Medicine. Looking ahead, the gtsummary performance collaboration is in progress, and the team expects a readout next month; a comprehensive tutorial and adoption guide is also planned, targeting a Q4 2026 publication. The proposed project end date remains Q2 2027.

Project Status

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